REMARKS

Claims 1-25 are pending in the application. Claims 14-17 and 18-25 have been previously withdrawn, by this Examiner, because of restriction requirements imposed in Office Actions dated February 17, 2004 and August 19, 2002 and therefore should not be acted upon by the Examiner. M.P.E.P. 821.

Unity of Invention Under PCT Rule 13.1

The Examiner contends that the application contains four groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1 and has requested restriction in accordance with 37 C.F.R. 1.499. The Examiner's four groups are:

(i) Group I: claim 4, "drawn to an azopolymer;"

(ii) Group II: claim 4, "drawn to a disulfide polymer;"

(iii) Group III: claim 6, "drawn to a methylmethacrylate or a copolymer of methacrylic acid and methylmethacrylate"; and

(iv) Group IV: claim 7, "drawn to a cellulose ester polymer."

The Examiner states that the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features for the following reason: they do not share common structure that defines the "special technical feature" necessary to specify a contribution of the prior art. However, the Examiner notes that claims 1-3, 5, and 8-10 are generic.

The applicants traverse the restriction requirement. The restriction requirement is improper on several grounds. First, the unity of invention standard under PCT Rule 13.1 is not applicable to this application. This application is a continuing application claiming priority to U.S. Patent Application No. 08/765,347 ("the '347 application"). The '347 application is a national stage application filed under 35 U.S.C. § 371; however, a continuation application claiming priority to a national stage application is not a national stage application; therefore, restriction practice under 35 U.S.C. § 121 is applicable and not the unity of invention standard. *See,* M.P.E.P. 1895.01. Thus, the Examiner has neither applied the correct standard to show that

restriction is necessary nor has she provided the correct evidentiary findings. Accordingly, the restriction is improper and its withdrawal is requested.

Moreover, even if the Examiner had applied the correct legal standard under 35 U.S.C. § 121, the restriction remains improper. To meet the requirements of § 121, the Examiner must demonstrate that the inventions are independent and distinct, and an examination of the unrestricted claims must impose a serious burden on the Examiner.

First, the restricted subject matter is not independent and distinct – each recites merely a coating material that may be used in the drug delivery system of claim 1. Contrary to the Examiner's assertion the claims are not drawn, *e.g.*, "to an azopolymer," but rather describe, *e.g.*, a drug delivery device having a coating that may contain, for example, an azopolymer.

Additionally, even in cases where claims containing a Markush group are directed to independent inventions, all members of the Markush group must be examined, provided, e.g., that the members are sufficiently few the member such that examination of the entire group can be made without a serious burden to the Examiner. M.P.E.P. 803.02.

In the present application, the Markush group (*i.e.*, the coating materials described in claims 4, 6, and 7) in question contains a mere four specific materials. Further, as these claims have already been searched, examined and the subject of two substantive Office Action, it is difficult to comprehend how, at this juncture the Examiner can assert that the burden is undue. The burden, if any, has already been undertaken.

For at least these reasons, the applicants submit therefore that the restriction is improper, and request its withdrawal.

Provisional Election

In the event that the Examiner makes the restriction requirement final, the applicants hereby provisionally elect for initial prosecution the claims of Group III, claim 6, drawn to a coating material of methylmethacrylate or a copolymer of methacrylic acid and methylmethacrylate.

Species Restriction under 35 U.S.C. § 121

At page 4 of the Office Action, the Examiner contends that the application contains claims directed to the following patentably distinct species of the claimed invention:

(a) vaccine;

(b) steroid, laxative, anticholinergic, opioid, calcium channel blocker, thromboxane A_2 synthetase inhibitor, and 5 HT3-antagonist;

(c) deoxyribonucleic acid molecule and an antibody against infectious bacteria;

(d) hydrocortisone, octreotide, cisapride, glucosamine, ridogrel, odansetron, and 5-ASA;

(e) budesonide;

(f) antibody against *Clostridium difficile*;

(g) antiviral agent;

(h) heparin, insulin, calcitonin, human growth hormone, growth hormone releasing hormone, an interferon, somatostatin, or an analogue thereof, erythropoietin, granulocyte colony stimulating factor, parathyroid hormone, luteinsing hormone releasing hormone or an analogue thereof, atrial natriuretic factor, vasopressin, desmopressin, calcitonin gene related peptide or an analgesic;

(i) octreotide, vapreotide or morphine;

(j) captopril, alfuzosine, bisphosphonate, carbamazepine, atenolol, raloxifene or benazepril; and

(k) clodronate.

The Examiner requires the applicants to elect a single disclosed species for initial prosecution on the merits.

The applicants hereby elect for initial prosecution on the merits of <u>claim 17, drawn to a drug delivery composition wherein the drug is budesonide.</u> Claims 1-3, 5, 8-10 and 18 are generic. Claim 17 is elected for initial prosecution without prejudice to the rejoinder of the remaining claims should the generic claims be found to be allowable.

CONCLUSION

In view of the foregoing, it is requested that the Examiner withdraw the Restriction Requirement and examine and allow the claims at the earliest opportunity.

Respectfully submitted,

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